SEP 2 6 2008

5. 510(k) Summary

Contact: Mr. Adam Herder
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Device Trade Name: SEEplate Cervical Plate System

Manufacturer: Amedica Corp.
615 Arapeen Drive, Suite 302
Salt Lake City, UT 84108

Classification: 21 CFR §888.3060, Spinal intervertebral body fixation orthosis

Class: II

Product Code: KWQ

Indications For Use:
The SEEplate Cervical Plate System is intended for anterior screw fixation at the vertebral bodies of the cervical spine (C2-C7). The SEEplate Cervical Plate System is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain in discogenic origin of the disc confirmed by patient history and radiographic studies), spinal stenosis, spondylolisthesis, deformity (defined as kyphosis, lordosis, and scoliosis), trauma (including fractures), tumors, pseudoarthrosis, and/or failed previous fusions.

This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. The device is intended for anterior cervical intervertebral body fusions only.

Device Description:
The SEEplate Cervical Plate System is comprised of an assortment of titanium alloy plates and screws that act to stabilize the spine during the intervertebral fusion process. The SEEplate Cervical Plate System is manufactured from wrought Ti-6Al-4V in accordance with ISO 5832-3.

Predicate Device(s):
The SEEplate Cervical Plate System was shown to be substantially equivalent to the Amedica Valeo Cervical Plate System (K071990) and has the same indications for use, design, function, and materials used.

Performance Standards:
Testing performed indicates the subject device is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2008

Amedica Corporation
% Musculoskeletal Clinical Regulatory Advisers
Mr. Adam Herder
1331 H Street Northwest, 12th Floor
Washington, District of Columbia 20005

Re: K082037
Trade/Device Name: SEEplate Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 15, 2008
Received: September 16, 2008

Dear Mr. Herder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

4. Indications for Use

510(k) Number (if known): K082037

Device Name: SEEplate Cervical Plate System

The SEEplate Cervical Plate System is intended for anterior screw fixation at the vertebral bodies of the cervical spine (C2-C7). The SEEplate Cervical Plate System is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain in discogenic origin of the disc confirmed by patient history and radiographic studies), spinal stenosis, spondylolisthesis, deformity (defined as kyphosis, lordosis, and scoliosis), trauma (including fractures), tumors, pseudoarthrosis, and/or failed previous fusions.

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Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082037